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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,283	09/19/2003	Kapil N. Bhalla	1372.76.PRC	2282
21901	7590	03/23/2006	EXAMINER	
SMITH & HOPEN PA 15950 BAY VISTA DRIVE SUITE 220 CLEARWATER, FL 33760			JAGOE, DONNA A	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/605,283	Applicant(s) BHALLA ET AL.	
	Examiner Donna Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/8/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-16 are presented for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "about" in claim 5 is a relative term which renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (MPEP 2173).

The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. When turning to the

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specification for guidance, it states that combined treatment with SAHA and imatinib mesylate for 48 hours induced more apoptosis of target cells as compared to the treatment with either agent alone (page 8). There is no recitation of the word "about". Because the term "about" has not been defined in a clear, objective manner, such would require subjective interpretations of whether or not a particular time frame is included by or excluded from the present claims or *why* such time frames would be included or excluded. It is therefore the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims and thus the claims fail to meet either the tenor or express requirements of 35 U.S.C. § 112, second paragraph and is properly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Emelen et al. U.S. Patent Application Publication No. U.S. 2005/0096468 A1 with a Provisional priority date of March 13, 2002 taken with Jolivet et al. U.S. Patent No. 6,645,972 with a Provisional Priority date of November 2, 2001.

Van Emelen et al. teach a combination (page 7, paragraph [0114]) of a Histone Deacetylation inhibitor (HDAC inhibitors) (page 6 paragraph [0084]) with another agent to treat cancer and cause apoptosis of cancer cells (page 6, paragraph [0085]) for *inter alia* leukemias (page 6 paragraph [0086]). Agents such as kinase inhibitors, for example imatinib mesylate are recited (page 8 paragraph [0128]) and HDAC inhibitors such as suberoylanilide hydroxamic acid (SAHA) are recited (Page 1, paragraph [0004] and page 8 paragraph [0149]) and a synergistic effect is achieved (page 9, paragraph [0159]). It does not teach exposure of the HDAC inhibitor and the tyrosine kinase inhibitor for about 48 hours, however, Van Emelen et al. teach administration of the agents "once, twice or more per course of treatment, which may be repeated, for

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example every 7, 14, 21 or 28 days. If the agent is administered daily, this would encompass exposure for about 48 hours (page 9, paragraph [0170]). It would have been obvious to employ the HDAC inhibitor and the tyrosine kinase inhibitor for about 48 hours motivated by the teaching of Van Emelen et al. that the HDAC inhibitors along with another chemotherapeutic agent, such as kinase inhibitors, for example imatinib mesylate are recited (page 8 paragraph [0128]) can be administered once, twice or more per course of treatment, which may be repeated, for example every 7, 14, 21 or 28 days. It does not teach the method where the cancer cells are imatinib mesylate refractory. Jolivet et al. teach treatment of acute leukemia is very complex (column 1, line 35) and resistance to agents occurs, particularly in Bcr-Abl tyrosine kinase inhibitor (column 3, lines 25-60) such as imatinib mesylate (column 2, lines 39-51). Van Emelen teach a synergistic effect when another medicinal agent and HDAC inhibitor are administered simultaneously or sequentially (page 9, paragraph [0159]). It is noted that there are other agents recited for treatment of cancer/leukemia. The claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts. It would have been obvious to one of ordinary skill in art at the time it was made to employ inhibitors of HDAC along with Bcr-Abl tyrosine kinase inhibitors to induce apoptosis in leukemia, as taught by Van Emelen et al. especially where there is resistance to the Bcr-Abl tyrosine kinase inhibitors, normally employed to treat leukemia and taught by Jolivet et al.

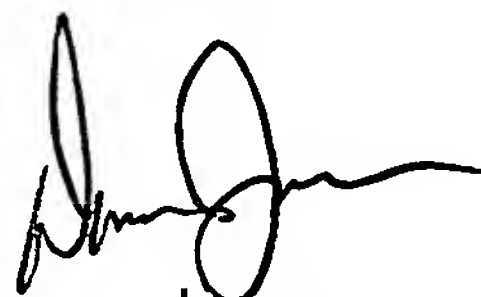
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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

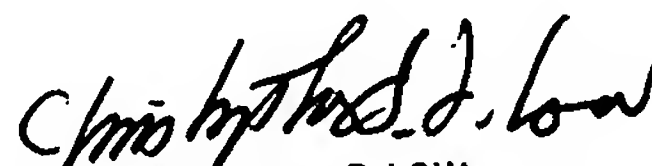
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Donna Jagoe
Patent Examiner
Art Unit 1614

March 18, 2006



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SUPERVISORY PATENT EXAMINER
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